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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,027	08/04/2003	Artem Gennady Evdokimov	9045M2	5050

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION - WEST BLDG.
WINTON HILL BUSINESS CENTER - BOX 412
6250 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1656	
MAIL DATE	**DELIVERY MODE**
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,027	EVDOKIMOV ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-32* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2007 has been entered.

The application has been amended as requested in the communication filed May 21, 2007. Accordingly, claims 1-9 have been canceled, and new claims 10-32 have been entered.

New claims 10-24 correspond to non-elected invention of Group III in the restriction requirement mailed January 19, 2006. Applicants' elected the invention of Group II, original claims 2 and 5, which corresponds to new claims 25-32, with traverse in the response filed February 13, 2006. The examiner responded to the traversal of the restriction requirement and made final in the first action on the merit mailed April 13, 2006. In response to the first Office action on the merit, applicants canceled all non-elected original claims 1, 3, and 4, and prosecuted only claims directed to the elected subject matter. Since the restriction was made final and no further appropriate action taken by the applicants, the finality of the restriction requirement is maintained and claims 10-24 are withdrawn from further consideration. Claims 25-32 are interpreted as directed to *in silico* method of identifying drug candidates.

Claims 25-32 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s). In particular, 37 CFR 1.821, which states:

> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Thus, each time in the specification the phrase "HPTPbeta" appear to refer to a specific amino acid sequence or nucleic acid in the sequence listing, a sequence identification number should follow the phrase.

In response to the above, applicants argue that they are not required to use sequence identification number after each occurrence of the term HPTPbeta, and cite MPEP section 2422.03.

Applicants arguments filed May 21, 2007 have been fully considered, but they are found unpersuasive. Since the sequence in question is part of the sequence listing, the application must comply with 37 CFR 1.821 (d). The citation from MPEP made by the applicant is taken out of context and it refers to a well-known sequence, which is not part of the sequence listing. In addition, the cited paragraph provides the examiner the tool to require the sequence identifier, if the sequence is deemed essential. In the instant case, the sequence is considered essential as well. Applicants must perfect their compliance with the sequence rules.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for rejections:

(a) The phrase "imaging, ..., a crystalline form of" in claims 25 and 26 is indefinite becuase the resulting claim does not define the metes and bound of the claimed invention. Computer modeling methods can use the atomic coordinates set forth in Figures 202-252 to image the three-dimensional structure of the HPTPbeta protein and not the crystal. The atomic coordinates are the property of the protein and not the crystal. The space group, the unit cell dimension, and the X-ray diffraction pattern obtained by exposing the crystal to X-ray (not reported in this application) are the properties of the crystal. Imaging a crystal on a computer screen would not be helpful in identifying any potential drugs, but imaging the protein structure is. For examination purposes only and in view of the elected subject matter in this application, part (a) of the method of claims 25 and 26 is assumed to mean -----construct a model of HPTPbeta using the atomic coordinates set forth in Figures 202-252---.

(b) The phrase "HPTPbeta catalytic domain" in claims 25 and 26 renders the claim indefinite because the resulting claim does not define the metes and bound of the claimed invention. The claim is not in compliance with the sequence rules and therefore is considered indefinite. Said catalytic domain is disclosed in the sequence listing it must be accompanied with a sequence identification number.

(c) Claims 27-32 are included in this rejection because they are dependent on a rejected claims and do not cure their deficincies.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen *et al.* [J. Med. Chem. 1990, 33 (3), 883-889] in view of Fachinger *et al.* (IDS reference 4: Oncogene 1999, Vol. 18, pages 1189-1198).

Cohen *et al.* the commercial availability of computers and various packages software used for imaging and identifying potential drugs using atomic coordinates of biological molecules. See in particular section VIII at page 893. This reference has an equivalent teaching to the admitted known prior art in the specification at 10, line11 through page 11, line 26.

Fachinger *et al.* teach a protein named VE-PTP and its functional interaction of a murine protein-tyrosine phosphatase with the angiopoietin Tie-2, see the abstract. Also, they teach that HPTPbeta is the human analog of VE-PTP and suggested that the human have the same function of VE-PTP in regulating Tie-2, see the paragraph that bridge the two columns at page 5952. Also suggested that HPTP beta has a possible role as adhesion receptor, see the previously cited paragraph.

Fachinger *et al.* provide one of ordinary skill in the art with motivation to identify potential modulator for HPTPbeta activity as they teach the biological role of HPTPbetal in regulating Tie-2, which is involved in vascolarization and remodeling of blood vessels. Thus, it would have been obvious to one of ordinary skill in the art to use a commercially available computer equipped with a software package such as GRAM, DUCK, QUANTA and AUTODUCK taught by Cohen *et al.* to fit a model structure of a potential inhibitor to the three-dimensional structure of HPTPbeta to identify possible modulator for HPTPbeta activity. The only difference between the cited prior above and the claimed invention are the atomic coordinates in Figures 7-102 and 202-252. Data, which are fed into known algorithm such as QUANTA whose purpose is to compare or modify those data using series of processing steps, do not impose a change in processing steps and are thus nonfunctional descriptive material. A method used for its known purpose to compare data sets does not become non-obvious merely because a new data becomes available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that has otherwise been obvious. See *In re Gulak*, 703 F2d 1381, 1385 (Fed. Cir. 1983). Atomic coordinate can't render a known method for identifying inhibitors of enzymes novel ou unobvious. It would have been further obvious to the ordinary skilled

artisan to synthesize the potential inhibitor and contacting it with HPTPbeta (claim 25-32).

In response to similar rejection of record, applicants argue that they have never agrees that computers and their software needed to carry out the method are known in the prior art and contended that the prior Office action did not identify which computers and software to use. Also, they argue that contrary to the examiner characterization of the atomic coordinates, the court found in *Gulak* that printed matter should have a patentable weight and should be considered in determining the patentability of the claims.

Applicants' arguments filed 5/21/07 have been fully considered, but they are found unpersuasive. The examiner is not quite sure about the applicants' argument with regard to known computers and their software. The specification clearly identifies the various software packages used for imaging the three-dimensional structure of a protein, as well as the software packages used for designing or identifying potential compounds that bind to a protein of interest. Do applicants disclose new software package or designed new computer that is disclosed in the specification and the examiner overlooked the new discovery? In any case, one of ordinary skill in the art armed with a set of atomic coordinates would have known the computer and the software package to use to carry out the claimed invention. This is evidenced by the new reference, which was published in 1990. A list of the software packages and their capabilities are provided at page 893. Probably, it safe to assume the capabilities of the listed software packages and computers has been enhanced since the publication of Cohen *et al.* 17 years ago. With regard to applicants' arguments regarding Gulack, the examiner has followed the directives of the court, MPEP section 2106.01, and the stated position of the U. S. Patent and Trademark Office in the trilateral report (See www.trilateral.net/projects/biotechnology/protein_3d/wm4_3d_annex_3.pdf). Section 2106.01 of the MPEP identifies to kind of descriptive material. The first is functional descriptive material, which causes a change to machine or a method. The second is a non-functional descriptive material, which does not change the method *per se.* In patentability determination, both kind descriptive materials have to be considered. The Office considers atomic coordinates non-functional descriptive materials because they do not change the functionality of the computer or the software it uses. See the trilateral report, in particular examples 6 and 7. Since a method of identifying inhibitors forHPTPbeta is obvious, the same method using the nonfunctional descriptive materials is obvious.

New claims 25 and 26 are directed to a method of identifying potential drugs using imaging of the atomic coordinates listed in the figures and produced from a specific crystal. The imaging methods of a protein structure using atomic coordinates are well known in the art at the time of invention. The citation in the claim that the atomic coordinates were obtained from a specific crystal does not change the claim because the claims are directed to a method of using atomic coordinates and not the

crystals. Applicants should be reminded that claims directed to using the crystal in a method of identifying potential drugs has been restricted out. See the discussion above.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nashed/
Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656